University of Alberta

Identification of Patient Safety Indicators in Capital Health Adult Cardiac Surgical Patients

By

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Abstract

Background

A reliable and objective method for identifying patient safety indicators (PSIs) could be used to evaluate patient safety improvement strategies in cardiovascular (CV) surgery.

Objective

To identify PSIs in Capital Health adult cardiac surgery patients.

Design & Methods

Agency for Healthcare Research and Quality (AHRQ) PSI software was applied to 5744 CV surgery cases from April 1, 1997 to March 31, 2002 in Alberta Provincial Project for Outcome Assessment in Coronary Heart Disease (APPROACH) and Capital Health administrative data. CV-specific PSIs including intra-aortic balloon pump (IABP), extracorporeal membrane oxygenation (ECMO) and wound dehiscence were identified by searching for corresponding International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) codes.

Results

AHRQ PSI rates exceeding expected included failure to rescue, decubitus ulcer, postoperative physiological/metabolic derangement and pulmonary embolism/deep vein thrombosis. Incidence of IABP, ECMO and wound dehiscence was similar to that expected.

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Chapter One

Introduction

Interest in patient safety is growing among health care professionals and the public. An indication that the interest is more than a fad was the formation of the Canadian Patient Safety Institute by the Canadian government in 2002. With a five-year budget of 50 million dollars established in 2002, the commitment to patient safety was made.[5] With any improvement project, baseline measurement is required before implementation in order to demonstrate effect. The Baker[5] Canadian Adverse Events Study established the cross-country reference point; overall, 7.5% of patients admitted to all Canadian hospitals and 10.9% of patients admitted to teaching hospitals, experienced adverse events. Baker[5] speculated that teaching hospitals had a higher incidence of adverse events due to a deficient risk adjustment model, higher patient acuity, patients transferred from other facilities at different points in care, patients receiving care from multiple providers affecting communication and care coordination, documentation practice differences across hospital types and a difference in quality of care. Baker[5] indicated that almost 185 000 of the 2.5 million annual acute care admissions in Canada result in adverse events and that between 9 250 and 23 750 patients die as a result of adverse events. Adverse events were defined as "unintended injuries or complications resulting in death, disability or prolonged hospital stay that arise from health care management".[5] The results provided by that Canadian study added to a set of international reference points currently used by individuals undertaking acute care quality improvement. Other landmark studies of adverse events using the same review tools have determined that the rate of

adverse events during hospitalization varied from 3.7% in the US[6, 7] to 10.8% in the UK[8] to 12.9% in New Zealand[9] and 16.6% in Australian hospitals.[10]

Cardiac surgical patients are at risk by the nature of their requirement for a surgery that involves opening the thoracic cavity, the pericardium and the use of cardiopulmonary bypass. As the co-morbidities and technical requirements of the patient stay become more complex, the risk for patient harm increases.[11] With the average age of patients increasing and life support capabilities in intensive and general care wards advancing while skilled staff shortages grow, the cardiac surgical patient's risk of suffering an adverse event while in a teaching hospital may be higher than the 10.9% expected based on the Baker[5] study.

Present Problem and Research

Patient harm due to medical error is not something that health care professionals are generally comfortable discussing or reporting. "The current legal and regulatory environment in health care perpetuates a fear of blame and litigation."[12] There are additional methods of finding key information about how patients suffer harm. The most common is individual chart review by trained reviewers. This method is time consuming and depends on high inter-rater reliability as well as the paper chart being available and complete. Another method that is gaining in popularity is computerized detection of adverse events, such as applying patient safety indicator (PSI) software to existing patient information databases.[1, 3, 11, 13-15] Free software is available from the Agency for Healthcare Research and Quality (AHRQ) to identify potentially preventable complications and iatrogenic events for patients treated in hospital.[16] The software is meant to identify the potential adverse events that are putting patients

at risk. From a quality improvement point of view, the use of indicator software is a way to establish priorities efficiently and reliably from a large data source.[1, 3]

Capital Health is a large regional health authority located in the central portion of the province of Alberta, Canada. It is Canada's largest health region, providing health services to approximately one million residents in the Edmonton area. It is also a referral centre to central and northern Alberta as well as parts of Saskatchewan, British Colombia and Canada's territories.[17] One of the specialized services offered is that of cardiac surgery. Within the Capital Health region, all cardiac surgeries are performed at the University of Alberta teaching hospital. The cardiac surgery program has a comprehensive database of patient information available. The combination of the AHRQ software and the cardiac surgical database could contribute to a routine database search for new quality improvement possibilities and evaluation of existing projects.

The Purpose of the Study

Building a Safer System[12] was a Canadian report released in 2002 that summarized the work of the National Steering Committee on Patient Safety and five of its sub-committees tasked with developing a national integrated strategy for patient safety. The report outlined the following components of a safer healthcare system; 1) System changes to create a culture of safety, 2) Improved measurement and evaluation processes, 3) Established educational and professional development programs, 4) Improved legal and regulatory processes, and 5) Improved information and communication processes. The purpose of the proposed study was to identify opportunities for improving cardiac surgical patient safety using the AHRQ software as a measurement and evaluation system. Hospital and health region administration is under pressure to determine

the most effective use of monetary and human resources. Identifying patient safety concerns provides the basis for resource allocation.[18] If a reliable method for identifying adverse events that hospitalized patients are at risk for were established, it would assist administrators to confidently allocate funding to implement system change to improve patient safety.[3] Opportunities for improvement obtained from this research will be a focus for further analysis, process change, policy change and education. Roles within nursing such as the clinical quality consultant or clinical nurse specialist can lead such multidisciplinary improvement initiatives toward optimal patient safety.

Abbreviations used throughout this document are provided in the following table.

Table 1. Common Abbreviations

Abbreviation	Intended Meaning
AHRQ	Agency for Healthcare Research and Quality
APPROACH	Alberta Provincial Project for Outcome Assessment in Coronary Heart Disease
ASD	Atrial Septal Defect
CH	Capital Health – Alberta Regional Health Authority
CABG	Coronary Artery Bypass Graft
CV	Cardiovascular
DVT	Deep Vein Thrombosis
ECMO	Extracorporeal Membrane Oxygenation
FTR	Failure to Rescue
HSPI	Health Services Planning and Information
IABP	Intra-aortic Balloon Pump
ICD-9-CM	International Classification of Diseases – 9th Revision - Clinical Modification
PE	Pulmonary Embolism
PHN	Provincial Healthcare Number
PSI	Patient Safety Indicator

Chapter Two

Literature Review

The literature review process started with the identification of variables and phenomena related to the safety of patients undergoing cardiac surgery. Those variables consisted of quality indicators, patient safety, harm, adverse events, clinical risk, preventable complications, safety management and medical error. The perspective of using administrative data for searches of adverse events was also covered by variables such as quality indicator software, computerized medical records systems, patient database, Agency for Healthcare Research and Quality (AHRQ), detection and information technology. All searches were combined with search terms for surgery and cardiac surgery in an attempt to find specific articles related to the identification of adverse events in cardiac surgery patients.

Literature Search Methods

Databases included in the literature search were Medline, PubMed, CINAHL and EBM Cochrane Collaboration Database. Reference lists of relevant primary and review articles on patient safety since 1990 were reviewed. Publisher web sites were used to identify papers that have referenced the key authors over the past five years. The names of expert authors on the subject of patient safety were searched in the above mentioned databases. The Capital Health Regional Quality Office staff was informally requested to search their own personal files and provide Health Canada, Canadian Patient Safety Institute and international documents relevant to patient safety.

Themes in the Literature

Patient Safety

The Canadian Patient Safety Dictionary (2003) defines patient safety as "the reduction and mitigation of unsafe acts within the health-care system, through the use of best practices shown to lead to optimal patient outcomes."[19] In 2000 the Institute for Medicine in the US published a report about patient safety converting the scientific results surrounding patient safety into a public report that received attention at the highest levels of government around the developed world when it revealed that between 44 000 and 98 000 Americans die each year as a result of medical errors.[20] That one report brought patient safety to the forefront of healthcare. The Institute of Medicine report referenced the research done by Brennan[6] and Leape[7] and made recommendations on how to act on the research. That report and the research it referenced provided the cornerstone of all patient safety research performed in the past decade. The effect in Canada was the formation of the National Steering Committee on Patient Safety in 2001. One of the recommendations of that committee was the establishment of the Canadian Patient Safety Institute to facilitate patient safety activities in Canada.[12]

The measurement of safety within an organization is the starting point of change toward improved care.[12] In order to see improvements, a baseline measurement is required. In 2004, the Canadian benchmark for adverse events during hospital stay was reported by Baker[5] at 7.5% in Canada. Of particular interest in similar studies done around the world are findings that 37% to 51% of the adverse events were preventable.[5, 6, 10, 21] Table 2 summarizes similar international studies. These established benchmarks are important from a comparison perspective for future investigations into the incidence of adverse

events during hospitalization. Patient safety during hospitalization is a significant concern that requires attention.

Table 2. Summary of International Adverse Events Studies

Author	Year	Country	Number of Charts Reviewed	Adverse Event Rate (%)	Preventable (%)
Baker[5]	2004	Canada	3745	10.9	36.9
Vincent[8]	2001	UK	1014	10.8	48
Davis[9, 21]	1998	New Zealand	6579	12.9	37
Wilson[10]	1995	Australia	14 179	16.6	51
Brennan[6] & Leape	1991	USA	30 195	3.7	not measured/reported

Culture of Safety

Reason[22] stated that "we can not change the human condition but we can change the conditions under which humans work". The system approach, which addresses the entirety of health care and its interdependent components,[19] is more likely to be successful than a focus on the individual.[11, 12, 22] The development of an organizational strategy for addressing patient safety culture requires work on multiple facets of a framework that influences clinical practice including 1) Patients and staff as individuals, 2) Team, organization and community, 3) Specification of components of individual major factors, 4) Formalizing and extending analysis of incidents and outcomes, 5) Systematic approach to risk assessment and 6) Error reduction strategies at organization and individual levels.[23] The proposed research includes the analysis of patient safety from a systematic approach. If successful, the findings can be used as

part of an organization level strategy to measure the overall quality of care delivered.

Recommendations from reviews of high profile critical incidents include organizational commitment to a safety culture by ensuring that staff know what to do following incidents, that they feel able to talk about concerns and that there is transparency and openness between patients, staff and management.[24-28] Safety research completed in other industries applies to healthcare, showing that errors fall into recurrent patterns regardless of who is involved. If employers encourage a blame-free culture, employees report incidents.[22] The reporting of incidents, if it were complete and reliable, would negate the need for searching the patient databases for adverse events.

To build a culture where effective patient safety attitudes exist requires a significant amount of organization commitment. The steps required to build a safe system include developing system wide leadership, culture, risk management, reporting error, communication, sharing safety lessons and implementing solutions.[25]

The building of a systematic approach to risk assessment and error reduction requires a supportive culture. It takes a just culture to identify adverse events and use the information in a non-punitive and constructive manner.[11, 12] The perspective from which errors are discovered and the existing management style determine the intervention. "Adverse events do not, of course, necessarily signal poor quality care; nor does their absence necessarily indicate good quality care."[6] Organizational culture is the driver of quality and patient safety initiatives. If health systems allow data to be analyzed for potential patient safety issues then improvements goals can be set.

Identification of Adverse Events – Technology and Chart Review

There are various methods of chart review to identify patient risk. They all require resources. The most reliable and cost effective method that retains usable information has yet to be determined. Traditional identification of adverse events has been accomplished with a two-stage retrospective chart audit. This method was used in the landmark US, UK and Canadian adverse events studies by Brennan,[6] Leape,[7] Vincent[8] and Baker.[5] A specially trained health care worker reviewed the patient chart and determined if there was evidence of an adverse event. The second stage was completed by a physician to determine if in fact an adverse event had occurred and the cause of the event.

A similar method, referred to as a trigger tool, describes the tool used to identify and quantify adverse event information collected during a two stage process.[18] The potential adverse events are listed as triggers on a checklist that is completed while reviewing random patient charts. All charts with positive triggers are reviewed to determine if the positive trigger was an adverse event, and if so, its preventability. The trigger tool can be administered electronically if the patient chart is available in that form. The tool is customizable for the changing needs of patient groups. The triggers focus on patient harm and the follow-up interventions include system based changes focused on improving patient outcome instead of only focusing on individual practice.

Multiple information technology programs are in existence that are intended to detect adverse events from administrative data bases. Most methods of screening for adverse events only screen for one type of adverse event, such as nosocomial infections, falls or adverse drug events. Until the electronic

programs are revised to capture multiple adverse events they will be of limited use in large, integrated health systems.[14]

Research into electronic screening of discharge summaries to measure adverse event incidence is in its early stages.[15] Developers of electronic screening tools are aware of the cost disadvantage of paper chart reviews by multiple reviewers. Electronic tools have been proven to be highly specific and reliable but require revision to improve sensitivity.[27] As development of electronic health records and adverse event detection software moves forward, identification of adverse events is expected to become more efficient.

International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) coding is a system first published in 1948, developed to build international capacity for comparison of morbidity and mortality statistics. Its development was a collaborative effort led by the World Health Organization. The ninth revision was released in 1977. Clinical modifications added to the basic statistical requirements for reporting provide clinical information that allows for classification of morbidity data for indexing of medical records, medical case reviews, and ambulatory and other medical care programs in addition to basic health statistics.[28] ICD-9-CM coding is applied by trained health records technicians. Diagnosis and procedure codes are assigned to patient charts after review of relevant operative reports, discharge summaries and other relevant sections of the chart. Research on the accuracy of coding has revealed that co morbidities tend to be underreported in the administrative (ICD-9-CM) data but specificity of diagnosis is high.[29]

AHRQ[30] is a US government funded organization whose main function is to help health care decision makers make informed decisions about improving the quality of health care services. AHRQ sponsors and conducts research that

provides evidence-based information on healthcare outcomes, quality, cost, use and access. AHRQ has developed software that can be applied to patient databases like that of the Capital Health cardiac surgery program, to identify patient safety indicators from the ICD-9-CM procedure and diagnosis codes assigned to the patient chart at discharge. AHRQ patient safety indicator software captures potentially preventable events that can affect patient safety where adverse event screening only captures actual adverse events.[31] Chart reviews that require extensive time, personnel and financing are not feasible in all organizations. Any resources saved could be used in the follow-up intervention phase. The AHRQ software is a potentially affordable method of identification of patient safety indicators.

Cardiac Surgery Quality

The nature of illness and being a hospitalized patient bears risk. Additional risk is involved in undergoing surgical intervention of any type. Cardiac surgery is a high profile specialty that receives a lot of attention, from a monetary and media perspective. In general, detailed patient information is available on the cardiac surgical patient that is not available in the general patient population.[32] The risk adjustment work done on cardiac surgical morbidity and mortality has enhanced data collection and has made this surgery population of interest from a patient safety point of view. Not only are the data available but the risk is known to be elevated as much as two to four times that of the average identified in the 2000 Institute of Medicine Report.[20] This higher incidence of error may offer enhanced opportunity for quality improvement initiatives.[33]

Adverse events happen even when people are doing their best to avoid error. It is impossible to measure every adverse event, potential or actual. It is,

however, important to assess patient care data for systematic problems that put our patients at risk.[23] Systematic electronic assessment can identify potential threats to patient safety[34] in a cardiac surgical setting.

Strengths and Limitations of the Literature

The literature surrounding patient safety and the culture that supports it is significant. Internationally, patient safety is a common topic for empirical research. There are multiple articles on tools available to measure adverse events and injuries to patients in hospital. One main theme appears when reviewing the literature, as stated in 2003 by Battles & Lilford, "no single method can be universally applied to identify risks and hazards in patient safety."[35] Development of methods for consistent identification of potential patient safety threats is in its early stages. Further investigation is required to establish a standard. It is likely that multiple approaches are necessary to obtain accurate results.

Summary of Findings and Gaps in the Literature

In general, the literature recommends that healthcare organizations work toward a transparent and trusting atmosphere where individuals are protected from blame.[22] Patient safety depends on the organization's culture. Systems of patient care continue to be a focus for investigation and improvement. Technology is one aspect of care that contributes to patient safety. There is no one method of measuring patient safety which will provide all of the answers but there are a number of possibilities that will provide a start to quality improvement. For the purposes of this study the free software available from AHRQ[16] is the most feasible tool to start searching the data available in Capital Health. As the

cardiac surgical service has an extensive database it is a logical place to start with a search for PSIs. To enhance the potential usefulness of the results of this study, three additional CV specific PSIs were added on advice of one of the local CV surgeons. The additional PSIs were incidence of intra-aortic balloon pump (IABP), extracorporeal membrane oxygenation (ECMO) and wound dehiscence.

Chapter Three

Conceptual and Operational Definitions

Table 3. AHRQ Patient Safety Indicators[1-3]

Patient Safety Indicator	Numerator Definition	Denominator Definition	Key Exclusions
Complications of Anaesthesia	Adverse effects of or poisoning by anaesthetic, endotracheal tube wrongly placed	All surgical discharges	Poisoning resulting from anaesthetic and any diagnosis of active drug dependency, active nondependent abuse of drugs or self inflicted injury
Death in a low mortality DRG	Discharge with disposition of deceased	Patients in DRGs with less than a 0.5% mortality rate based on NIS 1997	Trauma, immunocompromised state, cancer
Decubitus Ulcer	Discharge with decubitus ulcer	All medical and surgical cases with LOS 5 or more days	Admission from LTC or with hemiplegia, paraplegia or quadriplegia
Failure to Rescue	Discharge with disposition of deceased	ARF, DVT, PE, sepsis, pneumonia (including aspiration), shock, cardiac arrest, GI hemorrhage/acute ulcer	Patients 75 years and older, Patients transferred to an acute care facility, from an acute care facility, admitted from LTC
Foreign body left in during procedure	Foreign body accidentally left during procedure	All medical and surgical discharges	Patients with code for foreign body left in during procedure in principle diagnosis field
Iatrogenic pneumothorax	Iatrogenic pneumothorax	All medical and surgical discharges	Trauma, cardiothoracic surgery, lung or pleural biopsy
Infection resulting from medical care	Infection following infusion, injection, transfusion or due to vascular device or graft	All medical and surgical discharges	Cancer, immunocompromised state
Postoperative hip fracture	Hip fracture	All surgical discharges	Code for hip fracture in primary diagnosis field, cases where only OR procedure is hip fracture repair, disease or disorder of musculoskeletal system or connective tissue, principal diagnosis code for seizure, syncope, stroke, coma, cardiac arrest, anoxic brain injury, poisoning, delirium, other psychosis, trauma, metastatic cancer, lymphoid malignancy, bone malignancy, self-inflicted injury, patients less than 18 years
Postoperative hemorrhage or hematoma	Discharges hemorrhage or hematoma with surgical drainage or evacuation	All surgical discharges	Patients with postoperative hemorrhage or hematoma in primary diagnosis field, only operative procedure is postoperative control of hemorrhage or drainage of

			hematoma, procedure occurs before first operating room procedure
Postoperative physiological or metabolic derangement	Postoperative renal failure requiring dialysis or diabetic ketoacidosis, hyperosmolarity or hypoglycaemic coma)	All elective surgical discharges	Patients with ARF in whom a procedure for dialysis occurs before or on the same day as the first OR procedure, patients with both a diagnosis code of ketoacidosis, hyperosmolarity or other coma and a principle diagnosis of diabetes, patients with both a secondary diagnosis code for ARF and principal diagnosis of acute MI, cardiac arrhythmia, cardiac arrest, shock, hemorrhage, GI hemorrhage
Postoperative respiratory failure	Postoperative acute or acute on chronic respiratory failure	All elective surgery patients	Patients with acute respiratory failure in principle diagnosis field, where a procedure for tracheostomy is the only OR procedure, where procedure for tracheostomy occurs before the first OR procedure, patients with respiratory or circulatory diseases
Postoperative pulmonary embolism or deep vein thrombosis	Postoperative PE or DVT	All surgical discharges	Patients with codes for PE or DVT in principle diagnosis field, patients where procedure for interruption of the vena cava is the only OR procedure, patients where interruption of the vena cava occurs before or on the same day as the first OR procedure
Postoperative sepsis	Postoperative sepsis	All elective surgical discharges with LOS more than 3 days	Patients with sepsis or infection in principle diagnosis field, patients with an code for immunocompromised state or cancer
Postoperative wound dehiscence	Secondary procedure to close postoperative disruption of abdominal wall	All abdominopelvic surgical discharges	Patients in whom a procedure for re-closure of postoperative disruption of abdominal wall occurs before or on the same day as the first abdominopelvic surgery procedure
Accidental puncture or laceration	Discharges denoting technical difficulty (accidental cut, puncture, perforation or laceration) in any secondary diagnosis field	All medical and surgical discharges	Patients with codes denoting technical difficulty in principal diagnosis field
Transfusion reaction	ABO or Rh Transfusion reaction	All medical and surgical discharges	Patients with code for transfusion reaction in principal diagnosis field

Table 4. Definitions of APPROACH Priority Terms[4]

Term	Definition
Emergency	To be done without delay. Patient clinical status is one of ischemic (ongoing ischemia, evolving AMI, pulmonary edema) or mechanical (shock) dysfunction.
Urgent – In	In hospital/transfer: to be done prior to hospital discharge (not emergent and not elective). Procedure required during hospitalization in order to minimize clinical deterioration.
Urgent –Out	To be done on an urgent basis but patient came from home – next available time.
Planned	Low risk procedure could be deferred without cardiac compromise.

Methods

Study Design

A retrospective descriptive cohort study design was used to identify patient safety indicators (PSI) among the population of CV surgery patients at a large University teaching hospital between April 1, 1997 and March 31, 2002, the most recent five years that ICD-9-CM coding was used in Alberta. The study design was chosen based on the desired outcome being a description of the data as a means to identify PSIs in the population.[36] Although many quality improvement programs have reviewed charts in an attempt to measure PSIs in the hospital-wide and post surgical populations, this will be the first time that an electronic software program in combination with an administrative database will be used for detecting PSIs in the CV population.

Setting

The setting for this research was the CV surgery program at the University of Alberta Hospital in Edmonton, Alberta, Canada.

Study Subjects

All patients who underwent CV surgery between April 1, 1997 and March 31, 2002 were included in the study. So as to define a cohort who had undergone CV

surgery and had available administrative data, eligible subjects included all adult patients operated on through the CV program in the Capital Health region and recorded in the Alberta Provincial Project for Outcome Assessment in Coronary Heart Disease (APPROACH) registry.

APPROACH is a province-wide inception cohort of all adult Alberta residents undergoing cardiac catheterization for ischemic heart disease, for which data collection began in January of 1995. The APPROACH project was initiated to study provincial outcomes of care and to facilitate quality improvement for patients with coronary artery disease in Alberta. The APPROACH database contains detailed clinical information collected at catheterization and treatment on adult patients with known or suspected coronary artery disease. The data provide a unique opportunity to study outcomes in an unselected patient population with detailed clinical information.[37]

A total of 6193 procedure records from the APPROACH registry were matched with administrative data from the Health Services Planning and Information (HSPI) department of Capital Health. 97 cases were excluded based on receipt of single lung, double lung or combined lung and heart transplant surgery. An additional 353 cases were excluded due to lack of admission date, procedure date, diagnostic codes or procedure codes. The final case total used for analysis was 5743.

Consent

Patient consent for personal information accumulation in the APPROACH database is obtained at the time of cardiac catheterization for all patients. A Registered Nurse who was not directly involved in the APPROACH project explained the APPROACH database to the patient and provided them with an

information form to read. Once consent was obtained, the form was signed and a copy of the consent form was given to the patient for future reference.[37]

Data Collection/Procedures

Patient data was obtained from APPROACH including sex, date of birth, provincial healthcare number (PHN), discharge status, death date, procedure number, procedure date, surgery priority, surgery type and age.

The PHN, sex, date of birth, procedure number and procedure date from the APPROACH registry were merged by a health information analyst with the Health Services Planning and Information (HSPI) department of the health region, in order to obtain the patient specific administrative data containing the discharge abstract ICD-9-CM diagnostic and procedural codes. For the purposes of this analysis a data file of the merged data was created that included the patient chart number, sex, date of birth, admit date, discharge date, length of stay, diagnostic ICD-9-CM codes, ICD-9-CM procedure codes and procedure dates.

An Excel table was developed from AHRQ data element requirements and populated from the merged APPROACH and HSPI data. Each AHRQ data element was studied individually to determine if it was available to the researcher based on the merged file and what affect any missing data elements would have on the outcome of the study.[38] AHRQ data elements were defined as follows:

- KEY – The APPROACH procedure number was unique to each admission and was chosen as the key unique identifier for matching data from different sources.
- AGE – This field was populated by a calculated formula based on the date of admission available in the HSPI data.

- AGEDAY – The age of patients in days was calculated by a formula that was based on the day of admission. The field is meant to identify newborns in general patient data.
- RACE – This data is not collected by HSPI and was unavailable for this field. All cases were defaulted to 'other'.
- SEX – Males were recoded as 1 and females as 2.
- PAY1 – All patients were coded as 'medicare' to reflect the Canadian primary payer.
- PSTCO – This field was left blank as it pertains to US county postal codes for area level indicators and no equivalent Canadian code exists.
- HOSPID – The Alberta Health and Wellness identifier for the University of Alberta Hospital was used as the hospital identification for all patients as it was the only facility used for analysis in this study.
- DISP – The data was re-coded using death (20) and routine (1) disposition codes that matched the AHRQ software variables.
- ATYPE – Admission type was re-coded using the emergency, urgent and planned groupings that matched the software choices. APPROACH priority codes were used with emergency = emergency, urgent-in and urgent-out = urgent and planned = elective.
- ASOURCE – All patients were coded as Routine source of admission.
- LOS – The length of stay was calculated as that period of time between the admission and discharge dates, in days.
- APR_DRG –This field was left blank as the value is obtained by using additional third party software that was unavailable to the researcher. The PSI program does not use the data.

- SEVERITY – This field was left blank as the value is obtained by using additional third party software that was unavailable to the researcher. The PSI program does not use the data.
- RISKMORT – This field was left blank as the value is obtained by using additional third party software that was unavailable to the researcher. The PSI program does not use the data.
- DRG – Specific Diagnostic Related Groups relevant to CV surgery were applied according to surgery type. The list was limited to DRG 103-108, 110, 111 and 116, each matched to the appropriate surgical procedure from APPROACH.[28]
- MDC – All patients studied had CV surgical procedures therefore the Major Diagnostic Category (5 = circulatory system) was used for all patients.
- DX1-DX30 – The list of ICD-9-CM diagnostic codes from HSPI was transferred to this field.
- NDX – A count formula was used to count the total number of ICD-9-CM diagnostic codes for each patient.
- PR1-PR30 – The list of ICD-9-CM procedure codes obtained from HSPI was transferred to this field.
- NPR– A count formula was used to count the total number of ICD-9-CM procedure codes for each patient.
- PRDAY1-PRDAY30 – The number of days between admission and each procedure was obtained by calculating the days between admission and each procedure date in the data.
- YEAR – The year of discharge was applied to this field.

- DQTR – The calendar quarter of the patient discharge was applied to this field.

Chart Review of 50 random patient charts.

Fifty cases were chosen at random from the APPROACH data and corresponding patient charts were accessed through the Medical Records Department at the University of Alberta Hospital. Each chart was located on microfilm and reviewed by the researcher for incidence of the listed patient safety indicators from the AHRQ program. One chart was later excluded as the patient had undergone a double lung transplant. The final 49 charts were systematically reviewed in the following order:

1. Verify chart number
2. Verify PHN
3. Review surgical report
4. Review discharge summary
5. Review anaesthetic record
6. Review physician progress notes
7. Review medication order sheets
8. Review laboratory results
9. Review microbiology results
10. Review X-ray reports
11. Review blood bank product tags
12. Review nursing notes and assessment documentation

The main limitation to this method of review was the missing information from charts. When charts are microfilmed the facing pages of all contents is copied but the back sides of pages are not copied, leaving a large portion of information

unavailable. Information collected during this review was entered into an Excel spreadsheet for analysis.

Other Data Search – IABP, ECMO and Wound Dehiscence

Three additional searches were performed on the ICD-9-CM codes to locate cases containing intra or postoperative procedures including the insertion of an intra-aortic balloon pump (IABP), extracorporeal membrane oxygenation (ECMO) and patients with a diagnostic code for wound dehiscence. These three additional groups were chosen as they reflect CV surgery specific PSIs that are not identified by the AHRQ software.

Data Analysis

Data analysis was completed in the following phases: (1) Describe frequency of PSIs in the study population using the AHRQ program, and (2) Describe the associations between patient characteristics and the incidence of IABP, ECMO and wound dehiscence.

Phase 1

The first phase included reorganization of the APPROACH and HSPI data in order to run the AHRQ program to identify PSIs. The AHRQ PSI program was run in three separate steps to identify and calculate rates for PSIs. The first step was meant to assign 0 or 1 to PSI outcomes. The descriptive statistics identified all patients with co-morbidities such as hypertension, diabetes and chronic pulmonary disease. The file created during the first step is used in the program's second analysis to calculate observed rates. The results obtained from that program are used as a file that feeds the third/final program. The third program is meant to provide risk adjusted, observed, smoothed and expected provider level

PSI rates across stratifiers. The third program required observed rate output from the second program in order to be successful.[38]

The observed rates are dependent on results from running the first two programs and are calculated as a simple numerator/denominator using the PSI incidence divided by the number of procedures that provided a potential PSI. Output data and discharge status (alive/dead) are used to calculate PSI rates. The rates are calculated regardless of the number of cases available from the first two programs. AHRQ recommends that rates be used cautiously when less than 30 cases appear in the numerator or denominator.[38]

The risk-adjusted rates are dependent not only on the data obtained for the purposes of this research, but also on the baseline file provided with the AHRQ program that reflects the means and regression coefficients from a baseline database that represents a large proportion of the US population. The risk-adjusted rates account for the difference between the case mix of the baseline reference population and that of the data set used. In cases where there are fewer than three discharges for a PSI the risk-adjusted rate is set to missing.[38]

Smoothed rates come from the risk-adjusted rates where each rate is adjusted for reliability for each indicator, bringing less reliable indicators closer to the mean and avoiding yearly fluctuations. Expected rates are based on what the provider would achieve if it were the same in variables (DRG, age, gender and co morbidities) as the reference population with similar variables. The expected rates are not benchmarks but are useful for comparison given that this is the first time these PSIs have been used in this surgical group alone.[38]

All results obtained in this research are provider level. AHRQ area level results are intended to compare facilities or regions and depend on availability of

population data. American population data is accessible for the AHRQ program but no replacement data is available from a Canadian source. All CV surgery data for this study were obtained from one facility. All area level information and obstetrical variables have been excluded for the purposes of this project.[3]

Phase 2

Frequency tables were generated and measures of central tendency were determined. The categorical data including IABP, ECMO and wound dehiscence results were used to create cross tabulations and Chi Square tests to determine what associations existed between those variables and population demographics. For analysis, all cases were categorized according to surgery type and recoded into the following groups: 1) CABG, 2) CABG/valve, 3) Valve, 4) Congenital/ASD/Defibrillator Implant/Miscellaneous and 5) Heart Transplant. Significance was set at $p \leq 0.05$. SPSS (Version 14.0, Chicago, Illinois) was used for all data analysis in this phase of the study.

Reliability and Validity

The data collected for the APPROACH patient registry is entered at the time of patient presentation and treatment in the cardiac catheterization lab. Registered nurses and physicians working in that department enter the details of the patient encounter. CV surgery patient information is added to the database by data analysts who review the operative patient chart and enter the pre-operative, perioperative and post-operative data into APPROACH.[37]

The data obtained from HSPI is collected from individual hospital medical records departments after health records technicians enter the diagnostic and procedure codes appropriate to each patient visit upon discharge.

Ethical Considerations

Approval for the research was received from the Health Research Ethics Board at the University of Alberta. The APPROACH investigators agreed to provide data required for the study. In order to access Capital Health administrative data, administrative approval was obtained from the Northern Alberta Clinical Trials and Research Centre and operational approval was obtained from HSPI as well as the medical records department at the University of Alberta Hospital. The research project was also discussed with the CV surgery program director.

All identifying patient information was kept confidential during the research project. In order to obtain HSPI administrative data, PHN, sex, date of birth, procedure number and procedure date were shared from APPROACH as required for data matching. Only de-identified data was used in the final analysis. No direct patient contact was required for any part of the research.

Chapter Four

Findings

As mentioned in the methods chapter, the purpose of this study was to identify patient safety indicators (PSIs) in the adult CV surgery population who underwent surgery in the Capital Health region between April 1997 and March 2002. A free software program from AHRQ was used to identify a predetermined set of PSIs based on ICD-9-CM coding. Further investigation specific to CV surgical patients was carried out by the researcher to identify incidence of intra-aortic balloon pump (IABP), extra corporeal membrane oxygenation (ECMO) and wound dehiscence in the same population. Descriptive statistics and frequencies are described. Chi Square analysis was used to analyze the relationship between categorical variables and incidence of IABP, ECMO and wound dehiscence. Statistical significance was set at $p \leq 0.05$.

Initial analysis of IABP and ECMO data by fiscal year revealed a discrepancy, with one year showing no cases of IABP or ECMO. Further investigation with the assistance of HSPI revealed that the initial data had been obtained from a corrupt file. The initial data received was discarded and new data was obtained from HSPI. All findings reported were obtained using the replacement data.

Description of Subjects

Between April 1, 1997 and March 31, 2002 a total of 5743 patients who had CV surgery met the inclusion criteria for the study. The sample consisted of 1443 females (25.1%) and 4300 males (74.9%) ranging in age from 14.1 to 89.5 years (mean 62.9, median 64.7, SD 12.2), with 793 (13.8%) of the sample 50

years or younger and 238 (4.1%) over 80 years. Surgical procedures included 3492 (60.8%) coronary artery bypass grafts (CABG), 721 (12.6%) CABG/valve, 829 (14.4%) valve surgeries, 577 (10.0%) congenital, atrial septal defect (ASD) repairs, defibrillator implant, miscellaneous, and 124 (2.2%) heart transplants. The length of stay (LOS) ranged from 1 to 455 days with a mean of 12.3 days and median of 7.0 days. 4764 (83.0%) of those cases were alive as of March 31, 2006 and 979 (17.0%) of them had died. The procedure priority revealed 305 (5.3%) surgeries were done on an emergency basis, 4650 (81.0%) were considered urgent-in hospital, 778 (13.5%) were urgent-out of hospital, and 8 (0.1%) were planned procedures.

AHRQ Program

The descriptive statistics identified 5744 cases. The number of cases with each condition is listed in Table 5. The software identified a top five listing of co-morbidities that included hypertension (50.14%), diabetes (15.15%), chronic pulmonary disease (10.92%), peripheral vascular disease (8.60%) and obesity (6.86%). The software did not identify any cases with congestive heart failure, valvular disease, pulmonary circulation disease or acquired immune deficiency syndrome (AIDS). The researcher performed a search for the ICD-9-CM codes in the data set used to run the AHRQ program. Upon searching by ICD-9-CM diagnostic codes 885 cases were found to have CHF and 214 cases of pulmonary circulation disease were found. No cases of AIDS were found. A search for all ICD-9-CM codes related to valvular disease was not completed as it was assumed at least all valvular surgical cases should have been identified by the AHRQ program. In the PSI provider categories, there were no cases identified by the AHRQ program for postoperative respiratory failure,

postoperative wound dehiscence or transfusion reaction. A search by ICD-9-CM code revealed that there were 33 cases that contained the diagnostic code for postoperative respiratory failure, 57 cases of postoperative wound dehiscence and three transfusion reactions. See Table 6 for all relevant ICD-9-CM codes.

Table 5. Co-morbidities Identified by AHRQ Program

	# cases with co morbidity	%
Hypertension	2880	50.14
Diabetes	870	15.15
Chronic Pulmonary Disease	627	10.92
Peripheral Vascular Disease	494	8.60
Obesity	394	6.86
Hypothyroidism	374	6.51
Diabetes w Chronic Complications	372	6.48
Deficiency Anemias	267	4.65
Fluid And Electrolyte Disorders	229	3.99
Coagulopathy	210	3.66
Renal Failure	196	3.41
Other Neurological Disorders	120	2.09
Depression	116	2.02
Rheumatoid Arthritis Collagen Vas	91	1.58
Alcohol Abuse	85	1.48
Solid Tumor w/o Metastasis	50	0.87
Paralysis	40	0.70
Psychoses	24	0.42
Drug Abuse	19	0.33
Lymphoma	18	0.31
Chronic Blood Loss Anemia	15	0.26
Metastatic Cancer	14	0.24
Liver Disease	14	0.24
Weight Loss	9	0.16
Peptic Ulcer Disease X Bleeding	1	0.02
Congestive Heart Failure	0	0.00
Valvular Disease	0	0.00
Pulmonary Circulation Disease	0	0.00
Acquired Immune Deficiency Syndrome	0	0.00

Table 6. ICD-9-CM Codes – Searches Completed by Researcher

Diagnosis or Procedure	ICD-9-CM Code
CHF	4280, 4281, 4289
Pulmonary Circulation Disease	4150, 4151, 41518, 41519, 4160, 4161, 4168, 4169, 4170, 4171, 4178, 4179
Acquired Immune Deficiency Syndrome	042
Postoperative Respiratory Failure	51881
Postoperative Wound Dehiscence	9983

Transfusion Reaction	9996, 9997, 9998
IABP	3761, 3762
ECMO	3965, 3966

The PSIs identified in the AHRQ descriptive statistics included complications of anaesthesia (n=1), decubitus ulcer (n=10), failure to rescue (n=145), foreign body left during procedure (n=3), iatrogenic pneumothorax (n=5), infection due to medical care (n=23), postoperative hip fracture (n=1), postoperative hemorrhage or hematoma (n=25), postoperative physiological metabolic derangement (n=7), postoperative PE or DVT (n=61), postoperative sepsis (n=3), accidental puncture/laceration (n=176). Additional information is provided in Table 7, showing observed, risk-adjusted, smoothed and expected rates.

Table 7. AHRQ Program – Overall Results

	n	# PSI events	%	Observed Rate (per 1000)	Risk Adjusted Rate	Smoothed Rate (per 1000)	Expected Rate (per 1000)
Complications Of Anesthesia	5739	1	0.02	0.00	.245	.315	.555
Death In Low Mortality DRGs	0						
Decubitus Ulcer	5199	10	0.19	2.81	7.67	7.94	5.53
Failure To Rescue	503	145	28.83	372.09	402.68	332.45	97.08
Foreign Body Left In During Proc	5743	3	0.05				
Iatrogenic Pneumothorax	286	5	1.75	34.48	1.87	0.64	5.43
Infection Due To Medical Care	5052	23	0.46	0.00	1.94	1.95	4.83
Postoperative Hip Fracture	5677	1	0.02	0.00	0.20	0.21	0.24
Postop Hemorrhage or Hematoma	5738	25	0.44	2.55	3.05	2.73	3.11
Postop Physio Metabol Derangement	765	7	0.92	0.00	3.81	1.85	2.37
Postop Respiratory Failure	0						

Postoperative PE or DVT	5737	61	1.06	10.20	10.30	10.22	9.47
Postoperative Sepsis	701	3	0.43	0.00	5.15	5.68	8.31
Postoperative Wound Dehiscence	68	0	0	0.00	0.00	2.02	2.34
Accidental Puncture/Laceration	5740	176	3.07	35.71	7.24	6.64	15.29
Transfusion Reaction	5743	0	0				

Incidence of IABP & ECMO

Of the 5743 patients included in the study, 201 (3.5%) had an intra or post operative IABP alone inserted, 10 (0.2%) patients had an intra or post operative ECMO alone insertion and 10 (0.2%) patients had combined IABP and ECMO. ECMO and IABP ICD-9-CM procedural codes that were missing procedure dates were excluded from this study. When grouped by fiscal year the incidence of IABP insertion ranged between 22-54 per year , ECMO 1-3 per year and combined IABP/ECMO 1-3 per year.

The majority of each intervention group received their surgery within one day of admission ($p \leq 0.05$) with 55.7% of the IABP group, 40% of the ECMO group and 90.0% of the combined ECMO/IABP group having their surgery within one day of admission. The use of these interventions is significantly related ($p \leq 0.05$) to the patient LOS with the highest percentage of IABP patients (48.3%) having an extended LOS, between 11-30 days. The majority of ECMO patient (60%) LOS was 6-10 days. Combined IABP/ECMO patient LOS was less than 11 days (60%) while an additional 10% of these patients had a LOS of 11-30 days and 30% greater than 30 days.

Even though more male patients received IABP, ECMO or both, there was not a statistically significant relationship between sex and the use of these devices ($p= 0.523$). When all patients who received the devices were combined,

sex remained non-significant (p= 0.180). Surgery type was significantly related (p≤ 0.05) to the use of IABP. IABPs were most commonly used in CABG surgeries and combined CABG/valve surgeries. This was true for both males and females (p≤ 0.05). Women were significantly more likely than men (p≤ 0.05) to have an IABP inserted with valve surgery. Overall, the most IABP insertions occurred in CABG patients (n=119, 59.2%) followed by combined CABG/valve patients (n=42, 20.9%). Valve surgery followed with n=14 (7%) and heart transplant surgery with 13 patients (6.5%).

ECMO was used most frequently in the surgery groups with congenital/ASD/miscellaneous procedures (n=5, 50%), followed by heart transplant with n=3 (30%) and CABG and CABG/valve with one in each group (10%). Combined ECMO/IABP was most common in heart transplant patients with n=4 (40%), followed by CABG with n=3 (30%) and n=2 (20%) in the congenital/ASD/miscellaneous group and one (10%) in the CABG/valve group.

Patients who underwent surgery as emergency and urgent-in patients were more likely to receive IABP and/or ECMO. 71.5% of IABP, 50% of ECMO and 80.0% of combined ECMO/IABP were inserted on urgent-in patients. Priority was significantly related to the use of these therapies (p≤ 0.05). These therapies were also significantly (p≤ 0.05) related to the recipients being deceased with 51.7% of IABP patients, 60% of ECMO and 80.0% of combined IABP/ECMO patients having a death date in the APPROACH database. Most patients discharged alive after IABP had a LOS 11-30 days (n=75, 55.1%) and equal percentages (21.3%) stayed 6-10 days or >30 days (p< 0.05). Of the ECMO patients who were discharged alive, 60% (n=3) stayed 6-10 days and 40% (n=2) stayed >30 days. The majority (n=3, 75%) of patients discharged alive after ECMO/IABP stayed >30 days and the remaining one patient stayed 11-30 days.

Of the patients who died with IABP, 35.4% did so within 5 days, 15.4% died between 6-10 days 33.8% died within 11-30 days and 15.4% died after 30 days. All ECMO and ECMO/IABP patients who died (n=11) did so in less than 11 days ($p< 0.05$).

Age was recoded into groups of patients under 50, 51-60 years, 61-70 years, 71-80 years and over 80 years. Age groups were found to be significantly associated ($p\leq 0.05$) with use of IABP and ECMO post-operatively. The majority of IABP were used in age groups between 61 and 70 years and between 71 and 80 years while ECMO alone was most used in the under 50 year category. Of note, one patient over 80 received ECMO and seven received IABP. When age was cross tabulated with priority for surgery, a significant relationship existed. As patients age they are more likely to be considered urgent-in, likely related to increased number of co-morbidities and severity of disease. No patients over 60 years were considered planned. Only 8 patients in the study group were prioritized as planned.

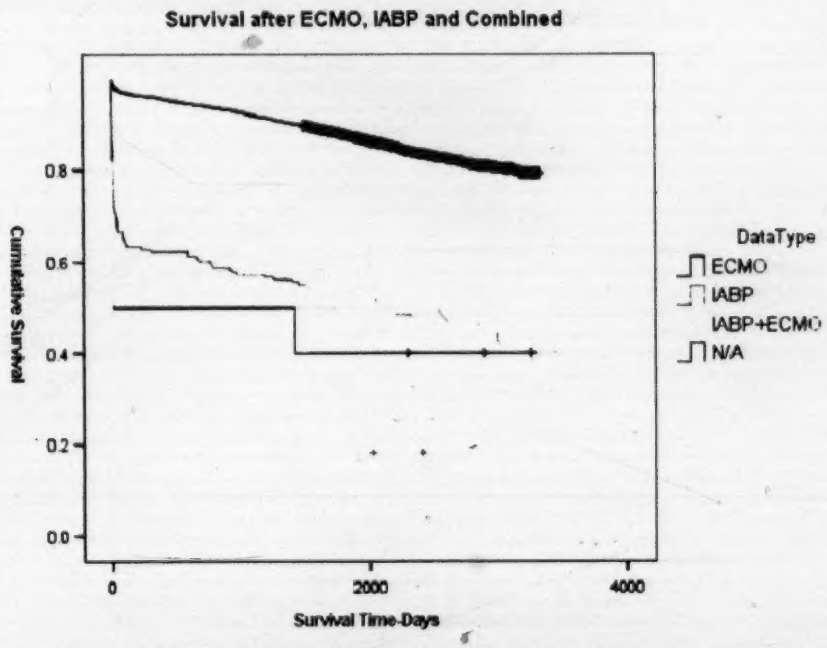
Table 8. IABP, ECMO, Combined IABP/ECMO & Wound Dehiscence

	n	# procedures with events	%
IABP	5743	201	3.5
ECMO	5743	10	0.2
Combined IABP/ECMO	5743	10	0.2
Wound Dehiscence	5743	57	1.0

A Kaplan Meier survival analysis shows a significant survival difference among the IABP, ECMO and combined IABP/ECMO groups (Figure 1). There is a significant disadvantage to receiving IABP, ECMO and combined IABP/ECMO procedures. The estimated survival time for IABP was 59.3 months, ECMO 48.2

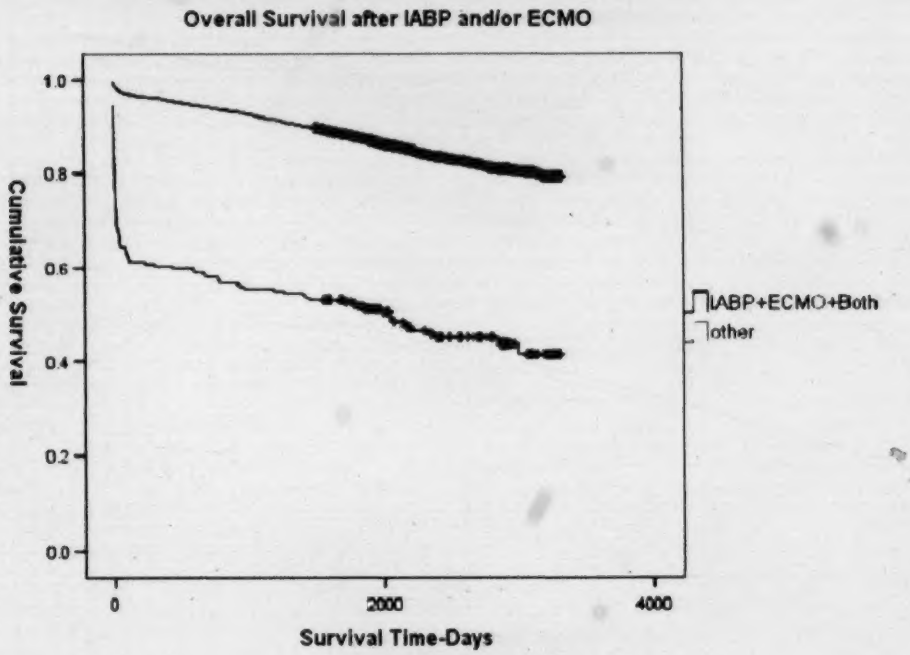
months and combined IABP/ECMO was 21.96 months. Estimated survival for patients without any of these procedures was 97.7 months. The log rank test of equality of the survival distributions was significant ($p < 0.001$).

Figure 1. Survival after ECMO, IABP or IABP/ECMO



A Kaplan Meier survival analysis performed on the same interventions as a combined group show a significant survival advantage for patients who did not undergo the procedures (Figure 2). The estimated survival of patients in the combined procedure group was 57.2 months while those patients without procedures had an estimated survival of 97.8 months. Again, the log rank test of equality was significant ($p < 0.001$).

Figure 2. Survival Combined IABP, ECMO & IABP/ECMO



Wound Dehiscence

Among the 5743 cases included in the study, 57 (1.0%) ICD-9-CM codes were found for postoperative wound dehiscence. Incidence ranged from 9-16 cases per fiscal year for the five years of data studied, a non-significant difference ($p= 0.488$). LOS for cases with wound dehiscence ranged from 6-235 days, with 52 cases (91.2%) staying more than 10 days, increasing LOS significantly ($p< 0.05$). Wound dehiscence was significantly ($p< 0.05$) related to surgery type, with more cases occurring in CABG (n=29, 50.9%) and CABG/valve surgery (n=17, 29.8%). Even though more males suffered wound dehiscence there was no statistically significant relationship between sex and the incidence of wound dehiscence ($p= 0.921$). The majority of dehiscence cases occurred in urgent-in patients (n=44, 77.2%) and urgent-out patients (n=8, 14.0%) but no significant relationship existed between priority of surgery and

wound dehiscence (p= 0.685). No significant relationship was found between dehiscence and number of days between hospital admission and procedure (p= 0.138) or age (p= 0.081). Of the total cases of wound dehiscence in the data set, 25 cases (43.9%) have a death date present prior to March 31, 2006. Of those deaths, only 5 (8.8%) were dead on discharge after surgery. A significantly larger (p< 0.05) portion of the dehiscence cases were discharged alive (n=52, 91.2%).

Incidence of Infection

Data obtained from Capital Health Infection Prevention and Control (IPC) included Blood Stream (BSI) and Surgical Site Infections (SSI). IPC follows CABG, valve and congenital surgery patients for SSI until discharge, with the exception of those admitted with bacterial endocarditis and patients who leave the operating room with open sternum postoperatively. All other surgery types were removed from the denominator. All positive blood cultures are reported to IPC, therefore all surgery types are contained within the denominator for the incidence of BSI. Data was only available for the fiscal years 1999 to 2002. Permission to obtain IPC data for the CV surgery program was obtained from the CV surgery divisional director as well as the IPC medical director at the University of Alberta Hospital.

Table 9. Surgical Site and Blood Stream Infection

	n	# procedures with events	%
Surgical Site Infection Apr 1, 1999 to Mar 31, 2002	3359	183	5.45
Blood Stream Infection Apr 1, 1999 to Mar 31, 2002	3653	34	0.93

Chart Review (50 charts reviewed by researcher)

In the group of 18 PSIs investigated, five contained discrepancies between the chart review and an ICD-9-CM search of the same group of

randomly chosen patients. One case of iatrogenic pneumothorax was found by ICD search whereas two were found during chart review, based on chest x-ray report. Infection due to medical care revealed no cases when searched by ICD-9-CM code but one positive strep viridans blood culture result was found during chart review. Postoperative hemorrhage or hematoma was found in four charts reviewed where the patient returned to OR and/or received 6 or more units of packed cells. Only three patients were found to have the code consistent with hemorrhage in the ICD-9-CM search of the same records. No respiratory failure cases were found on ICD-9-CM search but during chart review one case of pneumonia leading to prolonged ventilation was found. Accidental puncture or laceration was found during the ICD-9-CM search but no evidence of this event was found during chart review.

Table 10. Comparison of Chart Review & Data Search for ICD-9-CM codes

	Chart Review n=49	ICD-9-CM Search n=49
Complications Of Anesthesia	0	0
Death In Low Mortality DRGs	0	0
Decubitus Ulcer	0	0
Failure To Rescue	1	1
Foreign Body Left In During Procedure	0	0
Iatrogenic Pneumothorax	2	1
Infection Due To Medical Care	1	0
Postoperative Hip Fracture	0	0
Postoperative Hemorrhage or Hematoma	4	3
Postoperative Physio Metabol Derangement	0	0
Postoperative Respiratory Failure	1	0
Postoperative PE or DVT	0	0

Postoperative Sepsis	1	1
Postoperative Wound Dehiscence	0	0
Accidental Puncture/Laceration	0	1
Transfusion Reaction	0	0
Intra or Post operative ECMO	0	0
Intra or Post operative IABP	1	1

Chapter Five

Discussion of Findings

This descriptive study was conducted to identify PSIs in the Capital Health (CH) adult CV surgery population between April 1997 and March 2002. Using the AHRQ PSI program, a predetermined set of PSIs was identified from ICD-9-CM codes obtained from administrative data provided by HSPI. Further investigation specific to the incidence of IABP, ECMO and wound dehiscence was completed in a separate search for ICD-9-CM administrative diagnosis and procedure codes. Analysis of relationships between patient characteristics and the incidence of IABP, ECMO and wound dehiscence was conducted using Chi Square analysis. A 50-chart review was completed to assess the validity of ICD-9-CM coding.

AHRQ Program

The AHRQ program was successful at providing a snapshot of the incidence of PSI issues for adult CV surgery patients in Capital Health. Rates ranged from 0 for postoperative wound dehiscence to 402.68 per 1000 patients for failure to rescue. The risk adjusted results are similar to that of the Veterans Administration in the US[1] where failure to rescue (129.3-156.7 per 1000), decubitus ulcer (17.7-18.2 per 1000), accidental puncture/laceration (3.7-4.3 per 1000)) and PE/DVT (8.5-10 per 1000) accounted for the most frequent PSIs while complications of anaesthesia (.62-.86 per 1000) and postoperative hip fracture (.34-.67) consistently rated very low.

In the Capital Health CV surgery patients, decubitus ulcer (7.67 per 1000 patients) risk adjusted rates were slightly higher than expected (5.53 per 1000).

The denominator (n=5199) indicates that most of the patients with a LOS five or more days were captured by the program. A comparison with the APPROACH registry shows 5278 patients had a LOS of five or more days, a difference of 79.

The 145 cases of Failure to Rescue (372.09 per 1000 patients developing complications of care during hospitalization) is a PSI based on coding that has been established to be valid, supported with published evidence.[3] It is a PSI that could be investigated easily as all patients in the category have died (n=503). This PSI excludes patients 75 years of age and over (15.2% of the sample) which may affect overall rates for this study. The FTR PSI has strong evidence to support the notion that more hours and better skills in nursing and medical staffing result in fewer adverse events[39], as outlined by the AHRQ discussion on construct validity of FTR with respect to staffing.[3] Each of the clinical outcomes in the FTR denominator (pneumonia, sepsis, shock, cardiac arrest, DVT, PE, GI hemorrhage, acute ulcer, acute renal failure) could be targets for quality improvement, using the FTR risk adjusted rate as a measure of change.

The iatrogenic pneumothorax results are based on 5 cases, falling short of the 30 that AHRQ recommends as a minimum for making estimates. The exclusion criteria for the PSI include cardiothoracic surgery so the expected rate in this sample was zero. The denominator identified for the PSI was n=286, indicating that some of the CV surgical population was included in the program. That number is similar to the defibrillator implant group (n=289) raising the question as to whether or not the denominator consists of exclusively defibrillator recipients.

Postoperative physiological or metabolic derangement reveals a risk adjusted rate of 3.81 per 1000 discharges with an expected rate of 2.37. This result is suspect as the denominator is defined as all elective surgical discharges

occurring in the diagnostic related grouping (DRG). The AHRQ program identified n=765 as a denominator when only 8 patients are assigned a planned priority in the APPROACH registry.

There were 61 cases of postoperative PE/DVT (10.20 per 1000 surgical discharges with an operating room procedure) identified by the AHRQ program. The expected rate is 9.47 per 1000. AHRQ has identified this PSI as having an association with hospital processes and overall quality of care. The coding is thought to be valid.[3] Processes of care to prevent PE and DVT appear to be effective in this sample of CV surgery patients, with only a slightly higher risk adjusted rate in comparison to that expected.

PSIs, including complications of anaesthesia and postoperative hip fracture had lower risk adjusted rates than expected. This finding is consistent with that of Rosen[1] as well. Accidental puncture/laceration findings were lower than expected as well, likely due to the lack of coding for technical difficulty by medical records.

The AHRQ program failed to identify a number of co morbidities and PSIs that are expected in this population. The non-identification of co morbidities including CHF, valvular disease and pulmonary circulation disease indicates that the program needs further investigation. The most likely reason is that the coding of co morbidities within CH is not done in the same manner that the program requires for identification. A maximum of sixteen diagnostic codes are available from HSPI and any diagnoses in excess of this number are dropped from the data set.

Provider level indicators depend on a secondary diagnosis code that is associated with a preventable complication. If that diagnosis is not found in the maximum allowed 16 diagnostic codes available from HSPI then PSIs are

missed. Missing co morbidities could affect the risk related rates as the chronicity of the disease would not be taken into consideration.

The missing co morbidity details present an issue of questionable accuracy with the AHRQ program. Further analysis of the coding within the AHRQ program and within the medical records department would be required in order to establish the explanation for discrepancies between what was found and what was expected from the program. Until the coding within medical records is validated, it may be that the PSI scores are reflecting coding more so than actual PSI events.[1] One advantage to using the CV surgery patient population in Capital Health is that only one medical records department is responsible for coding as all CV surgery is performed at one hospital.

Accepting that the AHRQ program has limitations, there are still interesting findings in the results. In cases where the risk adjusted rate of a PSI is greater than the expected rate there are grounds for additional investigation. The PSIs that exceed the expected rates are decubitus ulcer, failure to rescue, postoperative physiological or metabolic derangement and postoperative PE/DVT. Additional investigation is required but the program provides a starting point for areas of focus.

IABP/ECMO Data

3.9% of the patients in this study received an IABP, ECMO or both. The LOS and mortality of this group is significantly higher than that of patients who did not receive any of these interventions. The significant association of these devices and overall mortality is demonstrated by the mean survival dropping dramatically from the time of procedure.

Intra and postoperative IABP insertion is an indication of serious complications which are often not correctable and end in high mortality.[40] The incidence of IABP use in this study was 3.5%, which is consistent with other multicenter studies involving Canadian CV surgery centers. (1.2 – 5.2%).[40] The use of IABP in this study was highest in the 60-80 year age range. IABP use was significantly higher in the CABG group followed by CABG/valve surgery patients, consistent with insufficient evidence for use associated with procedures other than CABG.[40] The LOS for the majority of the IABP group was in the 11-30 day range. The increase in overall LOS for the IABP patient requires additional allocation of resources that should be taken into consideration in program planning and management.[40] The literature on the use of IABP alone indicates that patients who survive to discharge have a good long-term survival compared to similar patients who did not have IABP.[40] Controversy about the indications for IABP and the notion that it is a complication rather than a therapy associated with CV surgery is apparent in the literature.[41, 42]

The use of ECMO was most common in the heart transplant and congenital/ASD/miscellaneous groups, in the age group under 50 years. That is consistent with the indication for ECMO being for acute, profound treatable insults to patients with healthy underlying cardiovascular systems. Survival was more likely in the heart transplant group (66.7%) than the congenital/ASD/misc group (40.0%). It would be useful to look at the incidence of ECMO in the current population of these patients to determine what their outcomes are and what factors made the difference between their staying less than 11 days versus >30 days in those discharged alive. It would be of interest to determine if the survival has improved since this study.

Combined ECMO/IABP was most common in CABG and heart transplant patients. This is consistent with the indication for IABP being primarily CABG surgery. When hemodynamic instability persists after IABP insertion, and maximal inotropic support, ventricular assist devices are the only likelihood of survival.[40] While only 40.0% of these patients were discharged alive, their LOS tended to be >30 days. Those who died did so within 10 days of their procedure. Of those patients who died, the majority were CABG patients whereas the majority of patients discharged alive were in the heart transplant group. Obviously the transplant patients had healthy underlying CV systems capable of recovering and the CABG patients suffered irreversible myocardial dysfunction.

While this data is of interest from a cost and human resources point of view, it is also of interest from a patient safety perspective. In a tertiary centre like the one studied it is important to know what the high cost interventions are that are being used, who they are used on, the indications for their use and their success rate. Rates over time are useful indicators of what types of patients are being seen in this area and how successfully the program is administered. Looking at the outcomes associated with interventions like IABP and ECMO in conjunction with the patient information available in APPROACH can help form the basis for guidelines for the use of such invasive procedures. The outcomes data can also be used as a reference when discussing expectations with patients and families.

Wound Dehiscence

The AHRQ results showed no wound dehiscence events, likely due to the program denominator definition including only abdominopelvic surgery discharges, excluding the CV surgery population on which this study is based.

ICD-9-CM code searching is a simple procedure as there is only one code for wound dehiscence. Results of the ICD-9-CM code search revealed an overall incidence of wound dehiscence of 1%. The overall incidence and significant relationship to LOS and CABG surgery is supported by previous studies.[43, 44] With 91.2% of cases staying more than ten days and 80.7% of cases occurring in CABG and CABG/valve patients, wound dehiscence is an easily identifiable PSI to measure without the AHRQ program and presents potential for focused improvement.

Incidence of Infection

Overall prevalence of wound infection after cardiac surgery (sternal and donor sites) ranges from 1.3% to 12.8%. As many as 50% of sternal and 80% of donor wound infections are diagnosed after patient discharge.[45] The incidence of blood stream infection according to data from the Capital Health Infection Prevention and Control (IPC) department was 0.93% over 3 years. The AHRQ results showed an incidence of 0.46% over 5 years. Possible explanations for the difference are that the positive blood result was obtained after the patient was discharged and was not added to the patient chart prior to coding, or the incidence of blood stream infection decreased over the five year period such that the AHRQ program reflects a lower overall incidence of blood stream infection. AHRQ excludes cases with codes for immunocompromised state or cancer which may have affected the overall incidence of infection. Positive cultures received by IPC pertain to all CV surgery patients and are only excluded if IPC determines that the result is hospital acquired. The difference in denominator between the IPC and AHRQ results may also be due to the AHRQ criteria being

confined to infection following infusion, injection, transfusion or introduction of a vascular device or graft.

Chart Review

The majority (72.72%) of PSIs observed during chart review were identified by searching appropriate ICD-9-CM codes contained in the AHRQ definitions. Five of the 18 PSIs contained a discrepancy. Four of those had one additional case identified by the researcher in comparison to that coded by health records. This discrepancy is likely related to the researcher searching the entire chart for PSIs whereas health records technicians rely primarily on operative and discharge summaries. The clinical experience of the researcher may have contributed to the identification of additional PSIs due to familiarity with the patient charts. Further investigation into the validity of coding in the CV surgery population would be of use. In order for PSIs to be identified through the use of ICD-9-CM codes, the application of those codes must be consistent.

Limitations

Coding

The coding of medical records depends on accuracy of discharge summaries dictated by physicians as well as coding by health records technicians. Summaries completed by physicians are expected to contain pertinent details of the patient's surgery, hospital stay and medical diagnoses. Health records technicians apply ICD-9-CM codes according to the details found in the discharge summaries provided. Generally, the technicians do not read the entire patient chart so detailed and accurate summaries are essential to ensure accuracy of administrative coding. Institution and individual practices vary with

regard to the completion of discharge summaries as well as assignment of ICD-9-CM codes. Training and experience are other possible factors that influence the integrity of administrative data. The first step in validation of any system that identifies PSIs from administrative data would be to assess the coding practices of the services contributing to the data.

The local practice of the surgeon or resident completing the discharge summary for a CV surgery patient's entire stay may be contributing to inaccuracy of the administrative data. An additional discharge summary from the ICU could identify diagnoses and procedures that are missed by the time a patient is discharged from hospital. It is documented in previous studies that adverse events lead to extended LOS and it is likely that the PSIs in this study contribute to an extended ICU LOS. The details of the PSIs may be lost among confounding details by the time a patient is discharged from hospital and therefore not coded.

Due to the discontinued use of ICD-9-CM coding in Alberta, the data used in this study may be outdated. No PSI program is yet developed that can be applied to ICD-10-CM discharge coding. It would be useful to have a program like that developed by AHRQ to apply to current ICD-10-CM codes to look at incidence and trends in PSI results in the CV patient population.

Scope of the Study

The PSIs discussed in this study are not an exhaustive list of all possible PSIs in the CV surgery patient population. The most obvious indicators not addressed are medication errors and falls. No references to CV specific staffing experience or education are available. The scope of this study was to see how an existing method of identifying PSIs would perform using CV surgery data, with the addition of a minimal set of CV specific PSIs.

Risk of Death

Although the AHRQ PSI program identified patients suffering death related to failure to rescue, the relative risk of death in CV surgery patients is not discussed. There is no linkage of PSIs to mortality at a population or individual level.

Clinical Significance

Without individual follow up and validation of the PSIs on a larger scale, it is difficult to comment on the clinical significance of the results. The risk adjusted results take into consideration the types of surgery and co morbidities of the patients in the study but without further investigation to link the results to individual patients' clinical significance can not be commented upon. However, the results do give an outline of where the further investigation could start.

An additional concern that requires further investigation is the reference population used by AHRQ. There may be significant differences between the CV surgery patient population (such as surgery priority) in the US compared to Canada. Any underlying discrepancy may have affected the results of this study with respect to risk adjusted and expected rates of PSIs.

Conclusions

The AHRQ program identified similar types of PSIs in the CV surgery population as in other large studies. With some further work to identify and validate additional CV surgery PSIs this program could be useful for focusing quality improvement initiatives. The program could be used on a regular basis to identify areas where improvement has occurred as well as where opportunity exists. It is one component of a comprehensive ongoing evaluation program. The

basic PSIs are relative to all surgical services and may be of use to programs other than CV surgery. Regular validation would be required to determine the clinical relevance of the identified PSIs. Consistent approaches to reviewing patient charts would be required prior to any action being taken on the results. It is unlikely that this program would be useful across sites or on a regional level, but use on a program level has potential. A registry such as that provided by APPROACH is useful for obtaining specific patient descriptors that are not available in regional or national level reporting databases.

The restriction in number of diagnoses and procedure code fields requires adjustment. The number of diagnoses and procedures that accompany a patient at discharge should have no maximum. The opportunity to describe the details that can lead to identification of PSIs is lost when a technician is restricted by capacity to enter data. In addition, the health records technicians responsible for assigning ICD-9-CM codes would be better served by a discharge summary that included details from the ICU stay. Immediate post-operative complications are diagnosed and treated in the ICU and should be reflected in a summary that is easily accessible to the health records technician. Microfilm practices could be improved in order to improve validation of results. The practice of incomplete chart scanning does little to assist the validation process.

The implementation of an electronic medical record will be an asset. Awareness of PSI programs such as that developed by AHRQ may assist in improvement of data quality while the electronic medical record is developed. Overall, this study has shown that there are opportunities for improvement in multiple aspects of CV surgery patient care.

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